

Rational Pharmaceutical Management Plus Democratic Republic of the Congo: Trip Report

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About RPM Plus

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, family planning, HIV/AIDS, Tuberculosis, Malaria and other infectious diseases, and in promoting the appropriate use of health commodities in the public and private sectors.

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Key Words

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Action plan

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Acronyms

AMO-Congo	Assistance medicale aux orphelins du Congo (Congo Medical assistance to orphans)
ARV	Anti retro-viral
BCG	TB vaccine
BCZ	Regional Central Office (Bureau Central du Zone)
CPLT	Regional Leprosy and Tuberculosis Office (Coordination Provinciale Lepre et Tuberculose)
CSDT	Health Center for Diagnosis and Treatment of TB
CST	Health Center for Treatment of TB
CTA	Ambulatory Treatment Center
D3/MoH	Third Direction of MS/Third Directorate of MOH
DOTS	Directly Observed Treatment Strategy
DRC	Democratic Republic of Congo
GDF	Global Drug Facility
GFATM	Global Fight AIDS Tuberculosis Malaria
INH	Isoniazide
IMR	Infant Mortality Rate
ISD	Supervisory Nurse of the District
ISP	Supervisory Nurse of the Province
IUATLD	International Union Against Tuberculosis and Lung Disease
LNR	National Laboratory of Reference
LNAC	Anti-Tubercular Patient and Anti-Leprosy National League of Congo
LPR	Provincial Laboratory of Reference
LAT	Anti-Tubercular Patient Fight
LMIS	Logistics Management Information System
MCP	Provincial Coordinating Doctor
MDR-TB	Multi-Drug Resistant TB
MMR	Maternal Mortality Rate
MS or MSP	Ministry for Health (Public)
MOH	Ministry of Health
ONG	Non-Governmental Organization (NGO)
OMS	World Health Organization (WHO)
PATI	Integrated Anti-Tuberculoses Program
PATIMED	Integrated Anti-Tuberculoses Drugs Program
PDDS	Master Line of Medical Development Program
PNAM	Access to Essential Drugs Program
PNT	National Program of Tuberculosis
PNLS	National Fight Against AIDS Program

PNUD	United Nations Development Program
REDSO	USAID Regional Africa Initiative
TDO	Directly Observed Treatment
TB	Tuberculosis
TLMI	Tuberculosis and Leprosy Mission
TLP	Laboratory Technician of the Province
UICTMR	International Union Against Tuberculosis and Respiratory Diseases
ZIEHL	Ziehl Neelsen Smear Examination Method
ZS	Health Zone

Acknowledgements to Collaborators and Partners

Special thanks to Thomas Moore, Etienne Bahati, Willy Kabuya, Michael Thuo, Michael Gabra for their useful advice and strong support and help in organizing this mission.

I would also like to thank all NTP team members and participants of the workshop for their precious contribution and team spirit.

BACKGROUND

The Democratic Republic of the Congo (DRC) health indicators are among the worst in Africa. In the case of Tuberculosis (TB) there has been considerable increase in the number of reported cases during the last ten years. For example, the MOH reported new smear positive cases for the year 2002 totaling 44,518 (including 10,710 cases from the city of Kinshasa alone). Some of the factors that contribute to the persistent high rates of TB infection include: the recent war and political instability; poverty (more than 70% of the inhabitants of the city of Kinshasa); low accessibility of the population to essential health services; and the prevailing high rates of HIV/AIDS infections.

At the request of the Ministry of Health (MOH/NTP) and USAID/REDSO the Rational Pharmaceutical Management (RPM) Plus Program was asked to carry out an assessment of the NTP TB drug supply system in Kinshasa in January 2004. Results confirmed the need for: (a) improved storage facilities for TB drugs at national and provincial levels, and (b) an improved management pharmaceutical management information system (PMIS) that can provide updated and accurate information on the **Quantity of Medicines Dispensed to Users, Average Monthly Consumption, Minimum/Maximum** quantities of TB drugs that must be kept in different types of facilities to assure drug availability and the **Existing Quantity** of Drugs in the MOH facilities at any point in time.

Purpose of Proposed Visit

This RPM Plus follow-up visit to Congo's National TB Program was designed for convening a stakeholders' meeting to present the assessment findings, discuss current status of the pharmaceutical management situation and develop an action plan to improve the situation. The visit was conducted by Joel Keravec with local assistance from Willy Kabuya, both Senior Program Associates with RPM Plus.

Scope of Work

The scope of work for Joel Keravec was as follows:

1. Prepare and conduct a stakeholders meeting :
 - to discuss findings and recommendations from previous RPM plus technical assessment
 - to prioritize the previously recommended activities for short and long-term assistance to fill existing gaps and identify the resources needed to support ongoing and planned activities
 - Develop an implementation plan
2. Brief USAID and TB partners interested in the above

ACTIVITIES

Prepare and conduct a stakeholders meeting:

(a) discuss findings and recommendations from previous RPM plus technical assessment, (b) prioritize previously recommended activities for short and long-term assistance to fill existing gaps and identify the resources needed to support ongoing and planned activities, and (c) develop an implementation plan.

Prior to the stakeholders' meeting RPM Plus's Senior Program Associate, Joel Keravec met with each of the stakeholders to discuss the workshop agenda and to complement the information obtained during the RPM Plus 2004 visit. See Annexes 1 and 2 for more information. The workshop agenda is in French.

TB drug management workshop

The one-day workshop was organized according to MSH's framework: Scan, Focus, Align and Mobilize, Plan and Organize. The meetings were attended by all the TB pharmaceutical management partners and the outcome at the end of the day was an action plan to strengthen TB pharmaceutical management in DR Congo.

Etienne Barati (NTP Director) presented the main aspects of the Strategic Analysis of TB drug management prepared by all partners in February 2005, and the vision of the NTP on priority challenges.

Joel Keravec of RPM plus presented the findings of the technical assessment in 2004 and main recommendations.

Partners discussed the TB drug management issues and challenges. Refer to the summary of the strategic analysis below:

Strengths	Weaknesses
<p><i>Drugs Selection Procurement and Quantification of Needs</i></p> <p>Standardized regimens recommended by WHO are in place</p> <p>Access to free medicines for TB treatment is guaranteed</p> <p>All TB medicines are registered (List of essential drugs/Pharmacy Department-MoH)</p> <p><i>Quality Control</i></p> <p>Quality control of TB medicines is currently realized by LAPHAKI and OCC</p> <p><i>Logistics and Management Information System for Drugs and Reagents & Drugs and Reagents Storage and Distribution</i></p> <p>A National Committee gathering all NTP partners (Patimed) is in place for harmonization and procedures definitions on TB Pharmaceutical issues like: quantification of needs , storage, distribution and use</p>	<p><i>Drugs Selection Procurement and Quantification of Needs</i></p> <p>Funding for procurement is dependent on external partners at 100%</p> <p>Delays between ordering and receiving at GDF are very irregular and jeopardize anticipated distribution plans</p> <p>No current funding assures sustainability of drug quality control (analyses are made without counter-payment from MoH and can be suspended any time)</p> <p><i>Logistics and Management Information System for Drugs and Reagents</i></p> <p>Lack of management logistics information from periphery level to central level : only 44% of the coordinations have data available on their inventory, 0 5 inventory data from Health Zones and Treatment Centers</p> <p>Internal procedures currently implemented among NTP and partners are not yet harmonized</p>

<p>A new version of the TB pharmaceutical Guide with harmonized procedures among partners is achieved and currently being printed in 2005 (Pati 4)</p> <p>2 pharmacists, one logistian and one warehouse manager available at the central level</p> <p>Procedures for supervision defined and harmonized</p> <p>Program evaluation regularly conducted and follow-up information available</p>	<p><i>Drugs and Reagents Storage</i> Storage capacity considered as insufficient Procedures between partners are different and not yet harmonized Storage facilities non secured, and not in conformity with current regulations Facilities are still under equipped (shelves, cold chain, work stations, transpalette manuel,...) Lack of training and capacity among human resources</p> <p><i>Drugs and Reagents Distribution</i> Process and distribution channels for drugs shipping from central level to periphery level are not yet integrated among NPT, partners like Damien Foundation and UNDP, and logistics usually made on a ad-hoc basis</p>
<p>Threats</p> <p><i>Drugs Selection Procurement and Quantification of Need</i> Permanent risk of withdrawal of partners' support Lack of guarantee of GDF drugs supply in a close future and risk of non-acceptation of the project submitted to Global Fund Stock-out for 2nd line TB drugs is announced</p> <p><i>Quality Control</i> Suspension of Drug Quality Control</p> <p><i>Drugs use and treatment regimens</i> Lack of knowledge at all levels for diagnosis, treatment and case management for chronic cases and MDR-TB</p>	<p>Opportunities</p> <p><i>Drugs and Reagents Storage and Distribution</i> Structuring process of PNAM offering new storage capacity and distribution channels Incorporate and strength contribution of provincial inspection pharmacist to foster drug management at periphery level Support of active partners for a common agenda on drug management</p> <p><i>Drugs use and treatment regimens</i> Current regimen change of 6 months vs. 8 months 1st line treatment creates better conditions for re-enforcing patient's adherence</p>

Based on the strategic analysis the following action plan was developed including parties who will be responsible for each activity. See Annex 3 for the complete plan in French.

- **Develop an information system (IS) for TB Drug Management integrated with PNAM and NTP partners**
- **Training key personnel on IS system use and implementation at all technical and operational levels for:**
 - Strengthening TB drugs Quantification and Procurement (first and 2nd line Drugs)
 - Reducing stock-outs through better reagents and drugs logistics for distribution procedures and harmonization among partners
 - Improving current storage capacity through better coordination among partners
 - Proposed methodology includes tools and training for improving workplace and skills for example:
 - Appropriate stock card or ledger for each drug and how to keep them up to date for drug receipts, drug dispensing and current stock position

- How to calculate average monthly consumption for each drug for stock level management
 - Requisition form and how to order drugs based on stock position each month, trimester, etc.
 - Checklist for keeping storeroom orderly, drugs safe from deteriorating, safe from theft, free from expiring, etc
 - Checklist for drug personnel to self-monitor
 - Checklist for supervisor to monitor drug personnel and storerooms
 - Checklist for monitoring expired drugs with the aim of reducing loss of drugs
 - ABC analysis for drug personnel to calculate value of drugs handled (sensibilization on costs if drugs are lost due to expiration, deteriorating or theft)
- Improving supervision by defining a set of indicators for monitoring and evaluation
 - Cost of expired drugs and supplies last month
 - Percentage of stock cards/ledgers up to date
 - Percentage of stock items that were out of stock at least once during the last period (month, trimester, etc)
 - Average wait time from time storeroom ordered drugs until they were delivered to them by the warehouse of higher level distribution center
 - Percentage of patients prescribed correct drugs for TB according to the National Standard Treatment Guidelines
 - Percentage of patients who understand how to take their TB drugs (would of course monitor this in treatment facilities not in warehouses)
 - Percentage of patients who reported DOT practice (they are observed directly by provider)
 - If a national TB guide or procedural manual is present in the treatment facility
 - If SOPs for drug management are available to drug personnel in warehouses and facility storerooms
 - Cost of drugs procured for use in country compared with International reference guide
 - Percentage of batches which were quality tested upon arrival into the country
 - Percentage of shipments where a batch certificate was received from supplier/manufacturer
 - Percentage of samples pulled for laboratory testing that were actually tested
 - Percentage of samples pulled for physical examination that were actually tested

➤ **Strengthening MDR-TB health surveillance at national level and the application of the national policy for a rational 2nd line drugs use and management (as recommended by Patimed)**

A cross-sectional survey was conducted in 1998 in Kinshasa on prevalence of MDR-TB among new and retreatment cases. Following results were registered:

- 2.2 % among new cases
- 22.1 % among retreatment cases

WHO standard treatment protocol is used to treat these MDR cases, but only Kinshasa Region is treating MDR cases to date. Estimated drug requirements according to the strategic plan 2006 -2010 have been included in GFATM proposal round 5. An adhesion application to the Green Light Committee has been introduced and currently waits for approval.

- **Supporting process of change in first line drugs regimen (6 months vs. 8 months) to improve patient adherence**
- National first line treatment protocol changed since 2004 and the technical guideline PATI IV was developed for implementation. However field implementation was one year postponed to allow consumption of EH (Ethambutol-Isoniazide) stocks. Progressive introduction of the new protocol (6months) is expected to start early 2006. GDF will continue assuring 2/3 of drug requirements one year more (till end of 2006), it has been providing this proportion of national TB drug needs since 2002 ; 1/3 of drug requirements is provided by usual partners including Foundation Damien, TLMI and ALM
 - A strategy for training all treatment centers will have to be developed with the edition of new guidelines.

Brief/debrief meeting at USAID mission

Joel Keravec, Etienne Bahati and Willy Kabuya held a debriefing meeting at USAID mission on August 12 with Health Officer Dr. Alethea Musah and Dr. Emile Bongo to discuss findings, workshop conclusions, draft of action plan for strengthening TB drugs management, main recommendations and next steps.

MAIN CONCLUSIONS AND RECOMMENDATIONS

A wonderful outcome of the workshop was the strong commitment among all partners to support the action plan for improving pharmaceutical management using the TB program as a model for strengthening other programs' essential medicines management in collaboration with PNAM and Third Directorate of MoH (D3/MoH).

Main recommendations are to focus on the following strategic objectives for a comprehensive approach to strengthen TB drugs management at all levels:

- 1. Hire a technical manager to work closely with the NTP and essential drugs program and other stakeholders to carry out this implementation plan and build long term capacity**

The NTP Coordination redeployed one pharmacist and two logisticians to be in charge of drug management improvement as recommended by the mission. These personnel have 3 years experience but need technical support and additional training and practice in their respective responsibilities.

- 2. Build a new strategic framework for rational pharmaceutical management at a national level integrated with the new Policy for Essential Medicines National Supply (PNAM) of MoH's D3 Direction**

In spite of its weaknesses, the NTP drug management program is the most advanced program for essential medicines in the DR Congo. The experience acquired by NTP and partners has to be incorporated in the process of discussion of a new drugs management framework that will benefit the other programs. The current PNAM program in its early phase of development has to be considered as a structuring opportunity since it presents the advantage of optimizing current storage capacity through a rational use of the existing capacity and can propose long term solutions to build reliable and regular distribution channels and transport conditions for TB medicines logistics. Harmonization of procedures and rational use of capacity among all partners for TB drugs distribution with PNAM's Regional Distribution Centers (CDR) and UNDP activities and funding is also highly suitable.

- 3. Improve management logistics information system (LMIS) on an integrated basis for all partners and develop an information system for TB Drug Management integrated with PNAM and NTP partners**

Feed-back from provinces and health zones is almost nonexistent for drug use, and existing stocks turning quantification of drug needs for TB control is a difficult exercise at NTP level. Damien Foundation has a central basic and efficient system based on an Access data base for drugs management at all its facility levels. It is used centrally for stock monitoring and distribution to the provinces supported by the DF, but is not implemented at the provincial level.

The pharmaceutical guide recently released by Patimed with all tools, policies and procedures for drug management will facilitate the outcome of system definitions for all technical and operational levels as described above.

LMIS will be based upon:

- exact understanding of current drug flow (who does what and using which tools)
- discussions and suggestions for tool changes, procedures if needed
- adaptation of the system and manuals to the agreed upon procedures and tools
- harmonization of a supervisory checklist and selection of a list of indicators prepared by drug personnel and sent to supervisor on a periodic basis for monitoring and evaluation

4. Foster Drug Quality Control and Drug Quality Testing Capacity

Encouraging international cooperation and providing technical assistance to the Office Congolais de Contrôle (OCC) to build more technical capacity and develop quality testing programs for essential medicines is a medium to a long term goal. Drug quality testing capacity is essential for further development of a rational pharmaceutical strategy for the DR Congo and needs advocacy among Ministries of Health and Finance leaders for better strategic definition and sustainable perspectives concerning investments and costs. The size of the country and multiple entries of medicines make this objective a real challenge, but some approaches used by RPM Plus in the SEAM program in Tanzania, for instance, could be applied in the DR Congo.

Current technical and management gaps for Quality System Implementation shall be identified using a comprehensive tool like the RPM Plus Management and Organizational Sustainability Tool for Drug Quality Testing Laboratory according international quality norms for a step by step process of implementing a rational quality control medicines program.

5. Support current process of change in first line drugs regimen (6 months vs. 8 months) to improve patient adherence and strengthen DOTS expansion

Progressive introduction of the new protocol (6 months) is expected to start early 2006. Developing materials for regimen change and supporting trainings for prescribers at treatment centers in Health Zones will be a key issue for achieving NTP targets in improving patient adherence and strengthen DOTS expansion. A short term technical assistance is essential to comply with this target: RPM Plus experience in designing workplans for drug use and educational strategies would be adapted for a quick response.

6. Strengthen MDR-TB diagnosis & treatment and cases management

Lack of capacity on diagnosis, treatment and management of MDR-TB cases is a global threat to public health, considering the results of 1998 study (- 2.2 % MDR-TB identified among new cases and 22.1 % among re-treatment cases). The discussion at the workshop revealed a rapid need of a comprehensive technical assistance for 2nd line TB drug management. RPM Plus developed new tools and DMIS for strengthening MDR-TB which could be applied to build capacity at national and regional level, through a medium to long term strategy.

NEXT STEPS

Immediate Follow-up Activities

- The participants of the workshop agreed on the need to create strategic working groups to address these issues and to promote the national strategy for pharmaceutical management

Agreement or Understandings with Counterparts

- MSH/RPM Plus was mentioned as a necessary partner to provide technical expertise and alongside the MOH to manage the implementation plan outlined in this report;
- MSH/RPM Plus will discuss with USAID the possibility of funding a pharmaceutical manager to guide implementation of the plan.

ANNEX 1

The following stakeholders provided the complementary information below to RPM Plus during the August 2005 visit (additional to that obtained in 2004):

Stakeholders

PNT Directors and collaborators:

Dr Etienne Bahati NTP Director
Pharmacien Ghislain Magata, Responsible for NTP Drug Management
Dr JP Malemba, Program Medical Supervisor
Dr JP Kabuayi, Program Medical Supervisor
Georges Kabuya, Head of the National TB Reference Laboratory

Ministry of Health

Dr Kasongo Elonga Kelon, Directeur de Cabinet Adjoint du Ministre de la Santé
Pharmacien Franck Biayi, / D3 Direction / 3rd Directorate
Pharmacien Mbeke / Responsible for the PNAM
Pharmacien Uteji / D3 Direction

WHO TB Managers

Dr Henriette Wembanyama,
Dr Flora Chirwisa

UNDP

Dr Victor Womitso-Mawulawoe, Team leader Portfolio/Global Fund
Dra Barbara, Drug Management/Global Fund

Clinique Université de Kinshasa (in charge of MDR-TB cases)

Dr Serge Bisuta

TLM

Dr Martin Ndombe, Director
Dr Axel Mawa, Deputy Director

Fondation Damien

Dr Pamphile Lubamba, Director
Dr Georges Bakaswa, Deputy Director
Dr Arakayo, Medical Supervisor

Office Congolais de Contrôle de Qualité

Dr Pintaba, General Director
Mrs Kabamba N'Sanga, Deputy Director
Bunda Dunia, Analyst
Pharmacien Mokelo Mumba, Head of Análisis Department

Coordinator of Kinshasa TB Program
Dr Bola

Ligue de la Lutte Contre la Tuberculose
Dr Gerard Kaboto, Director

MSH Office in DR Congo
Willy Kabuya

Complementary information on National TB Program organization and partners' interaction for TB drug management

All relevant information on NTP and partners activities are presented in RPM Plus assessment report of January 2004. We focused our observations on additional information on important points for the organization of the TB task force at each level like storage and distribution's system and description of the existing human resources identified as a potential for strengthening TB drug management.

Health Care System Organization

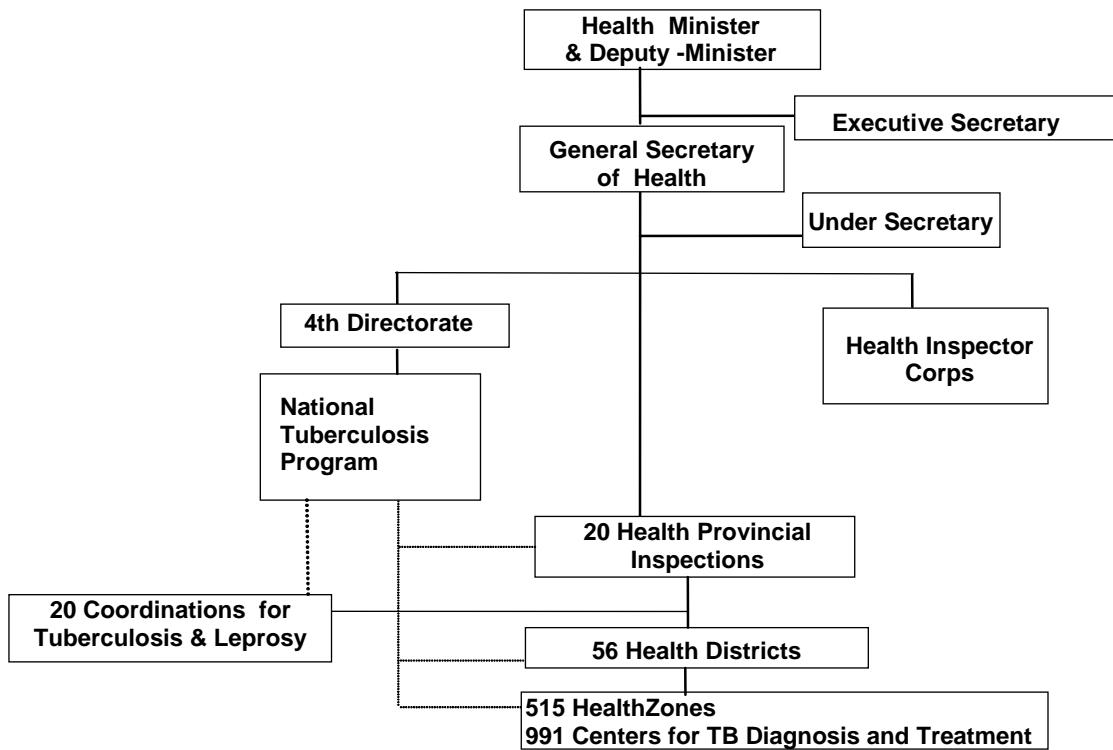
Basically focused on primary care management with very limited conditions of infrastructure, a national health policy is currently developed with the aid of partners to restructure health services through the country, but they are covering less than 20% of the population in urban areas.

Sanitary and Health Care system of DR Congo is composed of 20 provinces, 56 districts and 515 health zones (2004), with three levels of activity:

1. Central level: MoH, and General Health Secretary composed of 13 directorates and 52 programs for health policy definition and application
2. Intermediary level: provides technical support to health zones with 20 provinces and 56 health districts.
3. Periphery level: constitutes the operational level with 515 Health Zones, where Health Centers like Health Posts, Hospitals etc...are delivering primary health services to population, with specifically 991 Centers for TB Diagnosis and Treatment.

The figure below summarizes the basic organizational chart of Health Administration in the DR Congo and the NTP's articulation within the Sanitary Health System.

Figure 1. Organizational Chart of Health Administration in DR Congo



National Tuberculosis Control Program (NTP): structure, technical and operational levels, and mapping of key human resources available for TB drugs management

The National Tuberculosis Control Program (NTP) is one of the specialized programs under the aegis of the MoH's 4th Directorate (Directorate for Endemic Diseases and Medical Prevention); coordinates all TB activities at national level including management of the TB Task Force.

Main activities include:

- technical leadership for TB epidemiology and control in the DR Congo
- DOTS strategy implementation
- Management of TB drugs and reagents
 - selection, procurement, quantification and forecasts
 - distribution and storage coordination at all levels with partners
 - use of TB drugs by health facilities

Its structure includes National Bureau for Tuberculosis, the National Reference Laboratory, the Technical and Scientific Committee (local experts, international organisms and partners) and the Green Light Committee.

The National Tuberculosis Control Program (NTP) was initially established by the Ministry of Health in the 1980's, with technical and financial support from the Belgian Cooperation. In late 1990's, the Belgian bilateral agreement with the country's government stopped and since then, most of the financial and technical assistance to the program have come from donors through the

established non governmental organizations (NGOs). Some of the NGO partners that provide direct support to the NTP are also involved in diagnosis and treatment of leprosy (i.e. American Leprosy Foundation, and The Leprosy Mission International), and have long-term commitment to the country's health care system.

The National TB Reference Laboratory (LNR) is in charge of the quality control process (technical guidelines and human resources training, material and equipment, reagents) for all diagnosis and treatment centers using the technique of smear microscopy according to WHO and IUATLD recommendations.

NTP is structured and composed of 3 levels:

1. Central unit,
2. 20 intermediary Provincial Coordinations at the provinces level (Provincial Coordination: CPLT),
3. 515 Health Zones (ZS) - or sanitary districts according to WHO - with 991 centers for TB diagnosis and treatment (CSDT).

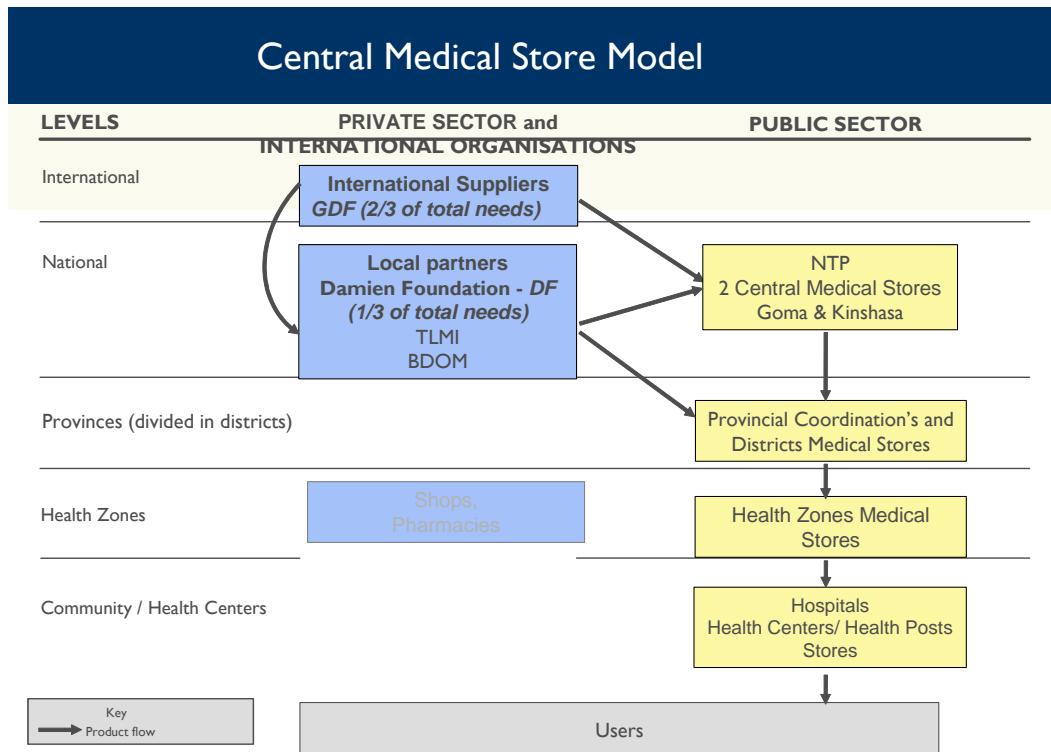
Central unit, Provincial Coordination and Health Zones are administrative and coordination structures for TB activities that provide technical support to the health zones. Eleven health provincial inspections have at least one pharmacist.

Centers for TB diagnosis and treatment are primary health care units or reference hospitals responsible for patients and cases management.

NTP structure and functions, roles and responsibilities of each level are summarized on the figure below, with identification of key human resources at every level for TB drugs management:

NTP Structure : Technical and Operational Levels			
Levels	Roles	Structures	Key Human Resources for Drug Management
National	Strategic Role: National Policy Definitions for Drug Management Coordination of all levels	National Program of Tuberculosis (NTP) <i>composed of :</i> National Bureau for Tuberculosis National Reference Laboratory Technical and Scientific Committee (local experts, international organisms and partners) Green Light Committee	PATIMED Drug Management Committee for Rational TB Drug Management and Policy Definitions - Includes NTP Directors, 3ème Direction/MoH and NTP Partners Central Medical Store 2 pharmacists + 1 logistician and 1 warehouse managers
Province (20) divided in Districts (56)	Technical Support to both programs TB and Leprosy Supervision of Health Zones	Provincial Coordinations for Tuberculosis and Leprosy (one or more per province depending on province size)	Provincial Medical Stores At least one MD Supervisor + 1 nurse supervisor + 1 lab technician
Health Zones (515)	Operational Level : technical support to Health Centers	Central Bureaus of Health Zones (515)	Health Zones Medical Stores 1 MD Supervisor Chief of Zone + 1 or more nurse supervisors
Health Centers	Operational Level : Health Posts, Hospitals Centers for Diagnosis & Treatment Centers for treatment	991 Centers for TB Diagnosis and Treatment (CSDT) Centers for TB Treatment (CT) (each one technically submitted to one CSDT)	Hospitals, Health Centers, CSDT, CT Medical Stores 1 MD Supervisor + 1 or more certified nurses + 1 lab technician for each CSDT
Users			

TB medicines Storage and Distribution model



Partnerships with donors and NGOs

Due to funding limitations and the expanded scope of the NTP activities in the country, the MOH was compelled to develop partnership with donors and NGOs to assist with the implementation and expansion of the NTP activities including the DOTS strategy. Partners that are extensively involved in the implementation of the program strategy and activities include WHO, UNDP, USAID, Damien Foundation, American Leprosy Mission, Appui aux Lepreux et Tuberculeux de l'Ituri, the Leprosy Mission International, GFTAM, and the International Union Against Tuberculosis and Lung Diseases (IUATLD).

The complete list of partners and their respective roles is presented in previous RPM Plus assessment reports(?)

The National Policy for Access to Essential Medicines (PNAM)

A new model for a national policy to enhance access to essential medicines is in a process of development. Its main principles are based on:

- Centralization of the procurement for all essential medicines through a federal agency (FEDECAME) for better quality assurance and price negotiation, more efficient transport facilities and custom fees exonerations
 - Autonomy of structure and financing
 - Interaction with all strategic partners through conventions
 - Re-structuration of the distribution model: creation of 40 distribution structures at regional level set in strategic cities, called CDR (mixed status: private structure but with a public mission and a recognition of public interest)
 - State will play a regulation function between CDR's federation, financial partners and users to guarantee the model as a sustainable public service, and to control and evaluate its quality
 - The model will incorporate all actual partners already acting in drugs distribution and provide adequate training
 - A trust fund will be created
 - The main clients will be: central bureaus of health zones, hospitals and health posts/centers, NGOs and faith based organizations, programs, firms, private health services. Eligibility criteria will be based on good management practices and system rentability
 - Technical and financial management assistance and trainings are required and will be delivered to all levels
 - Currently, 9 CDR are operational, 4 of them having already signed a convention (*)
 - FEDECAME in Kinshasa,
 - ASRAMES in Goma*,
 - CAMEKI in Kisantu*,
 - CADIMEK in Kananga*,
 - CADMEKO in Mbaji Mayi*,
 - CAMEBO in Matadi,
 - CEDIMET in Tshikapa,
 - CEDIMEK in Kamina,
 - CAMESKIN in Kinshasa,
- 2 CDR are not operational yet:
- CAMENBAND à Bandundu
 - CAMELU à Lubumbashi

**ANNEX 2 :
WORKSHOP PROGRAM**

**DÉVELOPPEMENT D'UN PLAN D'ACTION STRATÉGIQUE
CONCERTÉ POUR LA GESTION DU MÉDICAMENT
ENTRE LE PROGRAMME NATIONAL CONTRE LA TUBERCULOSE, LES
PARTENAIRES DU PNT E MSH/RPM Plus**

PROGRAMME DE L'ATELIER DE TRAVAIL

Date: 11/08/2005

Local: Salle de réunion SANRU - Kinshasa

Horaire: 9h à 17h

Participants:

Num	NOMS	ORGANISME
1	Dr Emile Bongo	USAID
2	Dr Etienne Bahati	PNT
3	Pharmacien Ghislain Magata	PNT
4	Dr Flora Chirwisa	OMS
5	Dr JP Malemba	PNT
6	Dr JP Kabuayi-Nyengele	PNT
7	Georges Kabuya	PNT/ Laboratoire
8	Dr Serge Bisuta	CUK (MDR)
9	Pharmacien Franck Biayi	3eme Direction (Minist. Santé)
10	Pharmacien Uteji	3eme Direction (Minist. Santé)
11	Pharmacien Mbeke	PNAM (Minist. Santé)
12	Pharmacien Matamba	PNAM (Minist. Santé)
13	Dr Martin Ndombe	TLMi
14	Dr Axel Mawa	TLMi
15	Dr Pamphile Lubamba	Fondation Damien
16	Dr Georges Bakaswa	Fondation Damien
17	Dr Valère Arakayo	Fondation Damien
18	Dr Valentin Bola	Coordination Provinciale Kin
19	Dr Gerard Kaboto	Ligue pour la lutte contre TB
20	Joel Keravec	MSH Brazil
21	Willy Kabuya	MSH RDC

Contexte de la réunion

Le Programme National de lutte contre la Tuberculose (PNT) a conduit une évaluation du programme en février 2005 avec la collaboration de l'OMS et de tous ses partenaires. Un groupe de travail composé des 12 consultants internationaux et 58 consultants nationaux ont visité 7 provinces dont 21 zones de santé, 42 CSDT, 17 écoles de Médecine, 7 Directions centrales et 14 ONG et associations. Le PNT a également redéfini ses objectifs pour la période de 2006 à 2010.

A cette occasion, le comité de gestion national des médicaments (PATIMED) a identifié un certain nombre de contraintes et défis liés à la gestion rationnelle du médicament :

- la quantification des besoins au niveau des centres de santé,
- l'harmonisation des procédures pour optimiser les délais d'approvisionnement,
- la gestion de la distribution et la nécessité de mettre en place de nouvelles procédures harmonisées et systèmes d'information entre les différents partenaires et acteurs pour un meilleur partage et circulation de l'information entre les différents niveaux de gestion
- l'utilisation des médicaments et la mise en œuvre d'un nouveau régime de traitement pour la première ligne (6 mois au lieu de 8 mois de traitement)
- le développement d'une politique d'action pour l'approvisionnement en médicaments de seconde ligne, un meilleur diagnostique, traitement et gestion des cas de tuberculose chronique et multi-résistante

De nouvelles procédures ont été définies et harmonisées entre les partenaires, un nouveau guide le PATI 4 est en cours de finalisation pour être distribué en 2005.

Au niveau du Ministère de la Santé, le Programme National du Médicament développe un nouveau modèle pour améliorer la gestion des médicaments essentiels et amplifier leur accès à la population.

Un consensus existe au sein des partenaires travaillant en collaboration avec le PNT: améliorer la gestion et la logistique du médicament est un des objectifs prioritaires pour renforcer le programme et la mise en œuvre de la stratégie DOTS.

Une réflexion concertée s'impose pour harmoniser ces nouvelles politiques et développer un modèle national de gestion du médicament, en utilisant l'exemple du PNT et son expérience dans ce domaine.

Usaid a financé une première mission d'évaluation du système de gestion et de logistique du médicament pour la TB en janvier 2004, et a sollicité à MSH un suivi pour discuter et réévaluer les conclusions de cette mission, ainsi que développer une analyse approfondie des problèmes rencontrés et des solutions à envisager pour développer un plan d'action concerté au sein du PNT et de ses partenaires.

Objectif Principal de l'atelier de travail

- Développer un plan d'action stratégique pour améliorer la gestion du médicament dans le contexte du Programme National contre la Tuberculose et de la nouvelle politique du gouvernement pour l'accès au médicament essentiel.

Objectifs spécifiques

- Analyser le contexte actuel et les actions entreprises par le programme et ses partenaires pour une meilleure gestion du médicament
- Analyser les problèmes identifiés, leur cause et leur conséquence pour le programme
- Prioriser les problèmes identifiés
- Evaluer des solutions possibles et présenter les outils de gestion rationnelle du médicament développés par MSH/RPM Plus
- Discuter la pertinence de ces solutions et leur adaptation dans le contexte de la RDC
- Discuter les rôles et la mobilisation des partenaires nécessaires dans la mise en œuvre des solutions proposées, et définir une matrice de responsabilités
- Développer un plan d'action avec les activités détaillées, les responsables, les ressources nécessaires et un chronogramme pour leur exécution

Organisation de la réunion:

9h00min

*Ouverture et présentation des participants – Dr Etienne Bahati
Méthodologie de l'atelier de travail - Dr Joël Keravec*

I. Première étape: définir le contexte

09h15min – Principales conclusions de l'évaluation du PNT faite en février 2005 - Dr Etienne Bahati

*09h30min – Problématique de l'approvisionnement en médicament et organisation de la logistique de distribution du PNAM en RDC -
- Pharmacien Mbeke*

*09h45min – Programme RPM Plus et Gestion Rationnelle du Médicament -
Concepts et principaux outils – Joel Keravec*

10h00 min – Discussion –

10h30min – Pause Café

II. Deuxième Etape: Identifier les problèmes prioritaires et envisager les solutions possibles

10h45min - Discussion

- Analyser les problèmes identifiés, leur cause et leur conséquence pour le programme
- Prioriser les problèmes identifiés en utilisant les critères de priorisation :
Amplitude : quels sont les niveaux où s'appliquent le problème rencontré, sa fréquence
Gravité : l'impact du problème
Existence et d'une solution
Faisabilité de la solution et identification des actions prioritaires
Capacité technique de mise en œuvre
Impact et potentiel
Ressources financières nécessaires
Délais d'application
Résultats espérés

12h30min

- Déjeuner

III. Troisième étape : Définir les rôles et responsabilités

13h30min- Discussion de la stratégie et de la matrice de responsabilités

IV. Quatrième étape : Elaborer un plan d'action et un chronogramme

14h00min- Identification et sélection des activités – Elaboration d'un plan d'action consolidé et d'un chronogramme

17h – Clôture de l'atelier

ANNEX 3

DEVELOPPEMENT D'UN PLAN D'ACTION STRATEGIQUE CONCERTE POUR LA GESTION DU MEDICAMENT ENTRE LE PROGRAMME NATIONAL CONTRE LA TUBERCULOSE ET LES PARTENAIRES DU PNT

Date: 11/08/2005

Problème	Action proposée	Type/Priorité	Ressources nécessaires	Responsable	Délai
Rupture de stocks au niveau central	Discuter avec le GDF la possibilité d'obtenir un meilleur contrôle des délais entre la passation des commandes et la livraison après l'estimation des besoins	1/A	-	PNT	Sept 2005
	Négocier la possibilité de pouvoir augmenter le stock de sécurité si les délais ne peuvent être garantis tout en gérant la date de péremption (marge d'action réduite)	1/B	-	PNT	Sept 2005
	Continuer à suggérer au GDF d'incorporer les formes pédiatriques dans les commandes	1/B	-	PNT	Sept 2005
	Faire un plaidoyer entre le Ministère de la Santé et le Ministère des Finances pour écourter les procédures douanières.	1/B	-	PNT	Sept 2005
	Renforcer le monitoring des stocks pour pouvoir redistribuer les médicaments entre provinces ou zones de santé dans les cas urgents		Système d'information opérationnel		
Absence de système d'information intégré	Sur le moyen terme, travailler la gestion intégrée des stocks avec les CDR		Système d'information opérationnel		
	Définir une méthodologie d'approche pour développer un système d'information intégré pour la gestion du médicament	3/A	AT MSH + Partenaires	PNT/PNAM/D5 – SNIS / D3	Oct 2005
	Réaliser un atelier de travail avec les partenaires pour analyser les procédures/outils de gestion du Patimed, analyser les supports d'information existants, et étudier les synergies possibles entre partenaires	3/A	AT MSH + Partenaires	PNT/PNAM/D5 – SNIS / D3	Nov 2005
	Incorporer au système une dimension nationale intégrée avec le PNAM	3/A	AT MSH + Partenaires	PNT/PNAM/D5 – SNIS / D3	Nov 2005 a mars 2006
	Développer toutes les procédures/outils de gestion pour un système d'information intégré à tous les niveaux	3/A	AT MSH + Partenaires	PNT/PNAM/D5 – SNIS / D3	Mars 2006

Problème	Action proposée	Type/Priorité	Ressources nécessaires	Responsable	Délai
Absence de système d'information intégré (suite)	Développer un support informatisé pour les outils de gestion et les procédures intégrés du nouveau système national au niveau central et provincial	3/A	AT MSH + Partenaires + Concepteur Informatique	PNT/PNAM/D5 – SNIS / D3	Mars 2006 à juillet 2006
	Définir les profils des opérateurs de ce système à tous les niveaux et des multiplicateurs potentiels	3/A	AT MSH + Partenaires	PNT/PNAM/D5 – SNIS / D3	Mars 2006
	Développer des modules de formation	3/A	AT MSH + Partenaires + Concepteur Informatique	PNT/PNAM/D5 – SNIS / D3	Juin 2006
	Editer et diffuser les matériels de formation	3/A	AT MSH + Partenaires	PNT/PNAM/D5 – SNIS / D3	A partir de juillet 2006
	Former les opérateurs à tous les niveaux pour chaque module	3/A	AT MSH + Partenaires	PNT/PNAM/D5 – SNIS / D3	Août à Septembre 2006
	Définir un nombre d'indicateurs pertinents et les modèles de rapports à transmettre à chaque niveau	3/A	AT MSH + Partenaires	PNT/PNAM/D5 – SNIS / D3	Mars 2006
Insuffisances dans la gestion du stockage des médicaments	Mettre en oeuvre un système de suivi et d'évaluation du modèle en place	3/A	AT MSH + Partenaires	PNT/PNAM/D5 – SNIS / D3	A partir de Septembre 2006
	Définir une méthodologie de formation basée sur les normes définies pour les bonnes pratiques de stockage	3/A	AT MSH + Partenaires	Patimed	Oct 2005
Insuffisances dans la gestion	Réaliser un atelier de travail avec les partenaires pour déterminer le profil et le nombre de ressources humaines destinées à être formé à ces normes	3/A	AT MSH + Partenaires	Patimed	Oct 2005
	Développer des modules de formation pour le stockage des médicaments et des réactifs	3/A	AT MSH + Partenaires	Patimed	Oct 2005 à Janvier 2006
	Editer et diffuser les matériels de formation	3/A	AT MSH + Partenaires	Patimed	Janvier 2006

Problème	Action proposée	Type/Priorité	Ressources nécessaires	Responsable	Délai
du stockage des médicaments (suite)	Former des gestionnaires de stock à tous les niveaux pour chaque module	3/A	AT MSH + Partenaires	Patimed	A partir de Mars 2006
Formation en gestion et stockage des médicaments	Harmoniser tous les modules de formation pour un programme de formation sur une semaine	3/A	AT MSH + Partenaires	Patimed	Entre Octobre 2005 et Mars 2006
Capacité et conditions de stockage des dépôts existants	Evaluer la capacité totale de stockage entre les différents partenaires et les CDR	3/A	AT MSH + Partenaires	Patimed	Oct 2005
	Etudier les possibles stratégies et modèles pour optimiser la capacité existante	3/A	AT MSH + Partenaires	Patimed	Nov a dec 2005
	Rationaliser le stockage des médicaments entre les différentes options offertes par les partenaires	3/A	AT MSH + Partenaires	Patimed	Jan 2006
	Evaluer les conditions de stockage et les besoins des dépôts existants (formulaires, visites)	3/A	PNAM+ Partenaires	Patimed	Oct 2005
	Réhabiliter les espaces fonctionnels existants pour les rendre conformes	3/A	AT MSH +PNAM+ Partenaires	Patimed	A partir de mars 2006
	Equiper les dépôts existants	3/A	AT MSH +PNAM+ Partenaires	Patimed	A partir de mars 2006
Interruption du Contrôle local de Qualité des médicaments	Faire un plaidoyer auprès du Ministère de la Santé pour trouver des partenaires capables d'assurer un appui technique et financier pour renforcer les structures de contrôle de qualité et la sécurité du médicament	1/A	-	D3 + PNAM	Sept 2005
	Editer et diffuser les matériels de formation pour le nouveau régime de traitement de 6 mois (Pati 4)	3/A	AT MSH + Partenaires	Patimed	A partir de Oct 2005

Problème	Action proposée	Type/Priorité	Ressources nécessaires	Responsable	Délai
Faible adhésion du patient au traitement	Former les professionnels de santé à tous les niveaux	3/A	AT MSH + Partenaires	Patimed	A partir de Oct 2005
	Organiser le suivi et l'évaluation	1/A		PNT	permanent
	Développer des stratégies pour renforcer l'adhésion au traitement : mobilisation sociale et communautaire	3/A	AT MSH + Partenaires	PNT	A partir de Oct 2005
	Développer des stratégies de motivation des professionnels de santé à tous les niveaux	3/A	AT MSH + Partenaires	PNT	A partir de Oct 2005
Prise en charge insuffisante des cas de TB-MR	Développer une stratégie pour un programme de vigilance épidémiologique des cas de TB-MR	2/A	AT MSH + Partenaires	Comite Feu Vert (GLC local)	A partir de Août 2005
	Implanter les tests de culture et sensibilité au niveau des laboratoires provinciaux de référence	3/A	GFATM + Partenaires (formation, labo, matériel et réactifs)	PNT	A partir de 2006
	Diffuser les directives et les supports d'information pour le diagnostic, traitement et accompagnement des cas de TB-MR	3/A	AT MSH + Partenaires	PNT	A partir de 2006
	Développer une stratégie de formation aux risques de la TB-MR pour le personnel de santé et de motivation des professionnels de santé à tous les niveaux	3/A	AT MSH + Partenaires	PNT	A partir de 2006
	A moyen terme, développer un système national d'information pour la vigilance épidémiologique des cas de TB-MR	3/A	AT MSH + Partenaires	PNT	Sept 2006
Rupture de stocks aux niveaux intermédiaires et opérationnels /	Soliciter une autorisation d'achat pour les médicaments de seconde ligne (les fonds sont réservés et disponibles depuis 2 ans) en attendant la réponse du GLC	1/A	AT MSH + Partenaires	PNT	Sept 2005
	Réaliser une analyse globale de la situation du transport de médicament à tous les niveaux avec une méthodologie adaptée	2/A	AT MSH + Partenaires	PNT	Oct 2005
	Etudier des solutions éventuelles en évaluant leur efficacité et efficience, compte tenu du contexte géographique et des acteurs potentiels (Partenaires privés et publics (PNAM, PNT), prestataires de service ...) pour les opérationnaliser	2/A	AT MSH + Partenaires	PNT	Nov 2005
	Choisir, prioriser et négocier avec les partenaires les solutions retenues pour un modèle national adapté à chaque contexte provincial	2/A	AT MSH + Partenaires	PNT	Nov 2005

Problème	Action proposée	Type/Priorité	Ressources nécessaires	Responsable	Délai
périphériques (Provinces, Zones de santé) <i>Absence de circuit officiel fonctionnel du Ministère de la Santé pour la logistique du médicament entraînant une coordination difficile entre les partenaires du PNT pour assurer le transport des médicaments</i>	Définir une matrice de responsabilités et réaliser une étude rationnelle des coûts de transport selon le modèle proposé Etablir un budget de transport à répartir entre les partenaires	2/A 2/A	AT MSH + Partenaires AT MSH + Partenaires	PNT PNT	Nov 2005 Nov 2005
Financement disponible insuffisant pour couvrir le transport régulier des médicaments au niveau central, de la province et de la zone de santé	Transformer l'étude des coûts et le budget nécessaire en mobilisation de ressources Inclure les coûts de transport dans les budgets des partenaires	1/A 1/A	PNT + Partenaires PNT + Partenaires	Patimed Patimed	Dec 2005 Dec 2005
Absence d'organisation au niveau opérationnel pour utiliser les moyens de transport déjà existants en périphérie	Identifier, et faire un mapping des moyens de transport existants au niveau opérationnel Définir une stratégie de synergie pour utiliser au maximum le transport de médicaments au niveau des déplacements prévus entre les différents services de santé	2/A 2/A	AT MSH + Partenaires AT MSH + Partenaires	Patimed + comités de coordination partenaires (IPS) Patimed + comités de coordination partenaires (IPS)	Oct 2005 Nov 2005

Problème	Action proposée	Type/Priorité	Ressources nécessaires	Responsable	Délai
Absence de procédures standardisées et d'indicateurs de monitoring pour évaluer l'efficacité et l'efficience du modèle logistique de distribution	Analyser les supports d'information existants au niveau du SNIS et étudier les synergies	2/A	AT MSH + Partenaires	PNT/PNAM/D5 – SNIS / D3	Oct 2005
	Définir un nombre d'indicateurs pertinents pour mesurer l'efficacité de la logistique de distribution (ligne de base / progrès)	2/A	AT MSH + Partenaires	PNT/PNAM/D5 – SNIS / D3	Nov 2005
	Développer un modèle de support d'information pour collecter les données nécessaires à une évaluation régulière	2/A	AT MSH + Partenaires	PNT/PNAM/D5 – SNIS / D3	Dec 2005
	Harmoniser les indicateurs avec le système d'information de logistique du médicament	2/A	AT MSH + Partenaires	PNT/PNAM/D5 – SNIS / D3	Dec 2005

– Legende : AT=Assistance Technique